K132347 NOV 2 0 2013 5-1

Inter Medical

510(k) Summary (21 CFR 807.92(c))

510(k) Owner's Name: InterMedical Medizintechnik GmbH
Daimlerstrasse 34-36
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Germany

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Establishment Registration Number: 3006611212

Date Prepared: 25 June 2013

Name of Device:

Trade Name: **MultiCam 3000 eco**

Common Name: Radiology Device

Classification Name: 21CFR 892.1200, Emission Computed Tomography System

Product Code: KPS

Identification of Predicate Device(s):

Manufacturer	Device Name	510(k) Number
Nuclear Cardiology Systems	Neurospect Quad Gamma Camera	K013353
Ohio Imaging	Prism 3000 Nuclear Gamma System Modification	K934722
InterMedical	CX 250 C Plus with Gamma XP Software	K052473

Device Description:

1. The MultiCam 3000 eco consist of the gantry with 3 Gamma Camera detectors, a patient table together with an Acquisition Workstation. The Performance or Quality assurance can be done on the Acquisition Workstation with the integrated quality software or on the connected Processing Workstations.
   The data will be transferred via the DICOM 3.0 Standard to a Nuclear Medicine Workstations of another Manufacturer, where the patient documentation will be done.

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2. The signal processing is done similar to the existing Prism 3000 or the CX 250 but on one high integrated board - LQN – which provides the Detector data via TCP/IP network to the Acquisition Computer. Also in the MultiCam 3000 eco a NaI crystal is used with 49 Photomultiplier. The Field of View is 13" x 7,9". Please refer for further details in the attached MultiCam 3000 eco Specification.

3. For the system there are 7 different collimators are optional available. The collimator exchange can be done manual. Each collimator has its own collimator switch which disables the dedicated motion over a separate electronic circuitry. The function of the collimator is also checked continuously by this safety circuits.

   The patient monitor is used for patient positioning. It consists of a color monitor for the display of the patient study during acquisition. Additional on it is a window with numeric information for the gantry motion information and the collimator information. It shows also Warning - and Error – Messages of the gantry.

   Functional characteristics: Each photomultiplier is precisely digitized with a resolution of 18 bit ADC's. No electronic is anymore needed on the photomultiplier. => Please refer the brochure 'LQN' our Camera electronic.
   The output of all 3 detectors are combined in a 1000 Mbit switch and connected over a proprietary TCP/IP network to the Acquisition Computer.

4. For the photographs see the attached MultiCam - Brochure, LQN - Brochure and further details are in the MultiCam 3000 eco Specification.

Intended Use Statement:

Multi Cam 3000 eco is intended to detect and obtain Planar - and SPECT Images of the distribution of a gamma emitting radionuclide in the organs or bone and store the data, when the radionuclide is administered in the body. Like all Gamma Cameras with the dedicated radiopharmaceutical it is possible to show functional imaging for diagnostic purpose. See also the indication statements of the predicate devices.

The MultiCam 3000 eco is due to the high resolution and sensitivity which are caused by the high number of photomultiplier per crystal field and the 3 detectors it is ideal for neurological and craniological functional diagnostic purposes

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Predicate Device Comparision

The purpose of this 510(k) is to inform the FDA of a new design similar to the following predicate devices

refer to 'Substancial Equivalent Discussion'

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Safety and Effectiveness:

The device has been designed, verified and validated complying with applicable safety standards for this type of medical equipment. Bench and clinical data demonstrate that images are equivalent resolution comparing to the predicate devices. No adverse effect has been detected. Additionally, a laboratory test has been carried out to validate the electromagnetic compatibility and biocompatibility by a third party organization.

Before placing the system on the market and use on human beings Inter Medical has reviewed all known information and carried out a risk analysis for the modified hardware.

Substantial Equivalency:

A matrix was made comparing the MultiCam 3000 eco to predicate devices and therefore we concluded that it is substantially equivalent to the legally marketed device.

(Signature)

Hans Guenter Osiek
(Typed Name)

15. April 2013
Date

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

InterMedical Medizintechnik GmbH
% Mr. William Carroll
Managing Director
Eclipse Systems, Inc.
14 Commercial Street, Unit B
BRANFORD CT 06405

November 20, 2013

Re: K132347
Trade/Device Name: MultiCam 3000 eco
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 26, 2013
Received: August 26, 2013

Dear Mr. Carroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

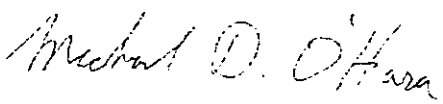
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k132347

Device Name: MultiCam 3000 eco

Indications for Use:

MultiCam 3000 eco is intended to detect and obtain Planar and SPECT images of the distribution of a gamma emitting radionuclide in the organs or bone and store the data, when the radionuclide is administered in the body.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) k132347